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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,964	11/08/2000	Philip A. Beachy	JHUC-P04-010	3944

28120 7590 12/20/2002

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BOSTON, MA 02110-2624

EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/20/2002

22

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/708,964

Applicant(s)

BEACHY ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,15-23,25 and 27-37 is/are pending in the application.
- 4a) Of the above claim(s) 2,18,19,25,29-35 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,15-17,20-23,27,28 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**Final Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***  
*20, 22, 23, 27, 28, 36, 37*

2. The rejection of claims 1, 15-17, 20-23, 27, 28 and 36 under 35 USC 112, first paragraph, scope of enablement, is maintained.

Applicant argues that (a) the rejection is moot with respect to claim 28 because it does not have a molecular limitation and (b) the present specification, coupled with information known in the art at the time of filing, sufficiently enabled the skilled artisan to make and use the invention commensurate in scope with the claimed invention. Accordingly, applicant argues that the test of enablement is whether the skilled artisan would be able to make or use the invention without undue experimentation and the present specification needs only to enable the skilled artisan to use the type of compounds claimed in the manner claimed. Applicant's argument was considered but not persuasive for the following reasons.

First, it is noted that the rejection states "[t]he instant claims recite the use of an organic molecule having a molecular weight less than 750 amu or a hedgehog antagonist". Therefore, the rejection is not moot with respect to claim 28.

Secondly, in order to practice the claimed invention commensurate in scope with the instant claim, the skilled artisan would first have to identify other

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compounds/molecules having a molecular weight less than 750 amu or that are hedgehog antagonists, from amongst the vast number of compounds known in the chemical art, that fall within the scope of claimed invention. It is the examiner's position that said determination is undue.

For these reasons and those given in previous Office Actions, the rejection of claims 1, 15-17, 20-23, 27, 28 and 36 under 35 USC 112, first paragraph, scope of enablement, is maintained.

28, 37

**3. The rejection of claims 1, 15-17, 20-23, 27, 28 and 36 under 35 USC 112, second paragraph, as being indefinite is maintained.**

Applicant argues that the skilled artisan would not be confused by the use of the phrases "inhibiting unwanted activation of a hedgehog-patched pathway" or "a purified organic molecule having a molecular weight less than 750 amu" and that the skilled artisan would have been able to make and use the entire scope of the claimed invention without undue experimentation. Applicant also argues that the phrase "prodrug form thereof" is defined by the specification. Applicant's argument was considered but not persuasive for the following reasons.

The definition of the terms "inhibiting", "unwanted" or "activation" or of the phrase "inhibiting unwanted activation of a hedgehog-patched pathway" is not at issue. The issue is whether the skilled artisan would know what is intended or encompassed by the phrase "inhibiting unwanted activation of a hedgehog-patched pathway". Apart from the specific examples disclosed by the present specification, such as unwanted cell

proliferation, the skilled artisan would be unable to determine the metes and bound of the claimed invention because he would not know what other conditions are caused by unwanted activation of said hedgehog-patched pathway.

Applicant also argues that the specification defines the phrase "prodrug form thereof". The present specification defines a "prodrug" as compounds that, under physiological conditions, are converted into the therapeutically active agents of the present invention. The specification does not set forth what compounds, under physiological conditions, are converted to said active agents of the present invention and, thus, it lacks guidance that would enable the skilled artisan to determine "prodrug form" of the claimed invention. Therefore, the skilled artisan in the art would be unable to determine the metes and bound of the claimed invention.

For these reasons and those given in previous Office Actions, the rejection of claims 1, 15-17, 20-23, 27, 28 and 36 under 35 USC 112, second paragraph, as being indefinite is maintained.

#### ***Double Patenting***

- ω 4. **The provisional rejection of claims 1, 15-17, 20, 21, 27, 28 and 36 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 09/708,974 is maintained.**

Applicant states that the issue will be addressed when the rejection is no longer provisional.

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5. <sup>21</sup> The rejection of claims 1, 15-17, 20-23, 27, 28 and 36 under the judicially created doctrine of obviousness-type double patenting over claims of US Patent No. 6,432,970 (Application No. 09/090,622) is maintained.

Applicant states a terminal disclaimer if necessary will be submitted upon indication of allowable subject matter.

W 6. The rejection of claims 1, 15-17, 20, 27, 28 and 36 under the judicially created doctrine of obviousness-type double patenting over claims of US Patent No. 6,288,048 is maintained.

Applicant states a terminal disclaimer if necessary will be submitted upon indication of allowable subject matter.

***Claim Rejections - 35 USC § 102***

7. <sup>1, 20, 36, 38, 39,</sup> The rejection of claims 1, 20, ~~21~~ and 36 under 35 USC 102(b) over Gerashchenko et al. is maintained.

Applicant argues that the reference does not teach or suggest every element of the present claims because it does not teach a method for inhibiting unwanted activation of hedgehog-patched pathway. Applicant's argument was considered but not persuasive for the following reasons.

Gerashchenko teaches the use of the claimed compound as an anti-inflammatory agent. Since a compound and its properties can not be separated, the skilled artisan would have the reasonable expectation that in vivo administration of the compound

would result in exertion of all of its actions, including the inhibition of hedgehog-patched pathway as recited by the instant claims. Applicant has not provided any factual evidence that the claimed compound given as taught by the reference does not inhibit the activation of a hedgehog-patched pathway.

Applicant's argument in regard to **Marshall** is noted. However, the issue in the present case differs because the claimed invention is a method of inhibiting a pathway, i.e., a mode of action of a compound, and is not limited to a single use of an old compound. Applicant is claiming inhibition of unwanted activation of a pathway that might be involve in a vast number of disorders, known and unknown. There is no indication that said inhibition is not advantageous in control of inflammation. The fact that the reference does not teach the compound would inhibit the activation of hedgehog-patched pathway does not imply that it does not because a compound and its actions are not separable. The ordinary artisan in the art would have the reasonable expectation that the various actions of the compound, including that recited by the instant claims, would be exerted once said compound is given in vivo.

For these reasons and those given in previous Office Actions, the rejection of claims 1, 20, 21 and 36 under 35 USC 103(a) over Gerashchenko et al. is maintained.

### ***Claim Rejections - 35 USC § 103***

**8. The rejection of claims 15-17 under 35 USC 103(a) over Gerashchenko et al. is maintained.**

Applicant's argument and the examiner response are as discussed above in #7.

For these reasons and those given in previous Office Actions, the rejection of claims 15-17 under 35 USC 103(a) over Gerashchenko et al. is maintained.

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

### ***Telephone Inquiry***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

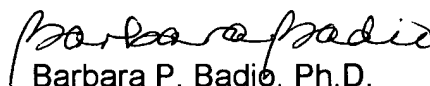
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for



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the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Barbara P. Badie, Ph.D.

Primary Examiner

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BB

December 20, 2002